

PSJ3  
Exhibit 349

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**From:** Tuszynski, Allison <atuszynski@hdmanet.org>  
**Sent:** Monday, October 27, 2014 4:41 PM  
**To:** Ducca, Anita; Kelly, Patrick  
**Cc:** Lankford, Elizabeth A; Gallenagh, Elizabeth; Bellingham, Daniel  
**Subject:** GAO Meeting Summary

Anita and Patrick,

Please see below a summary of the GAO meeting that took place at NASCSA. The attendee list is not exhaustive as a full attendee list was not made available. Further, several people arrived late and did not fill out name tags. If you have any questions, please let me know.

Thanks,

Allison

Summary of GAO Meeting  
October 22, 2014

Attendees:

Lindsey Jones, Kathy Hunter, Nicole Harrington -CVS Pharmacies  
Brian Rucker - Independent Pharmacy Cooperative  
Kent Hughes, Wade Lewis, Kaushik Kotecha, Winn Martin, Pamela Needham - Smith Drug Company  
Michael Clarke - Actavis  
Doug Lang - Express Scripts, Inc.  
Reckitt-Benckiser Pharmaceuticals  
Jack DeCiccio - GlaxoSmithKline  
Alan Must - Purdue Pharma, L.P.  
Kaleo Pharma  
Allison Tuszynski, Elizabeth Lankford -Healthcare Distribution Management Association  
Walmart

GAO asked three primary questions:

1. What issues, including drug abuse and diversion, are you in contact with DEA most at present?
  2. What have been your experiences with the registration process at DEA?
  3. Are there any other high-level issues with DEA that we should know about before we dive deeper into our investigation?
- Several attendees emphasized that wholesalers and dispensers are not receiving enough information from DEA on what constitutes a suspicious order. One person made the point that each companies' suspicious order monitoring program is based upon 59 words in the CFR.
  - Attendees pointed out discrepancies between the information and procedures used by DEA HQ and DEA field offices, noting that they "march to different drums."

- One manufacturer stated that during a meeting with DEA, they received the impression that DEA believes that if manufacturers make the controlled substances, it is up to them to determine what to do about drug abuse/diversion. DEA expressed in this meeting that the manufacturer could voluntarily reduce their quota as a means of tackling the problem.
- Attendees noted that DEA often declines to interface with registrants, trade associations and other stakeholders. A former DEA official who recently moved to the private sector at the meeting stated that this was typical for HQ to discourage field agents from granting meeting requests.
- One attendee noted that all of the problems that are currently happening at DEA are a “top-down” issue.
- Smith Drug gave several examples of how their interactions with DEA have been unsatisfactory. To explain why further clarification of SOM is needed, Smith mentioned how they have had to cut off a pharmacy in the past simply because of one bad physician. The one bad actor in a certain area was over-prescribing, but due to the demand because of his/her prescriptions at the pharmacy, Smith felt that they needed to cut off the entire pharmacy.
- One attendee noted that he had submitted a FOIA to obtain ARCOS data, yet the request had been denied. Other attendees mentioned that DEA is unwilling to share aggregated ARCOS data, or even pull out trends from ARCOS data to share with industry, which would allow industry to learn about and react to trends.
- HDMA was asked if we have any comment on the registration process, however we noted that as a trade association we are not involved in registration.
- Overall, it was a good meeting and HDMA expressed our willingness to assist should GAO have any further questions or would like another meeting. GAO estimated that the report will be released in Fall 2015.

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